

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

ASTELLAS US LLC; ASTELLAS
PHARMA US, INC.; and GILEAD
SCIENCES, INC.,

Plaintiffs,

v.

APOTEX INC., et al.

Defendants.

REDACTED - PUBLIC VERISON

C.A. No. 18-1675-CFC
(CONSOLIDATED)

APOTEX'S RESPONSE TO PLAINTIFFS' MOTION TO COMPEL

Dated: July 6, 2021

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Dear Judge Burke:

Plaintiffs argue that Biophore's voluntary production of documents in response to a subpoena in the Apotex Case creates a legal right for Apotex to obtain additional documents from Biophore (a foreign drug substance manufacturer) [REDACTED]. Apotex respectfully requests that the Court deny Plaintiffs' motion because: (1) Plaintiffs cite no authority for their novel argument; and (2) under the correct legal standard, Plaintiffs have not proven that Apotex has any "control" over Biophore [REDACTED] let alone the "control" necessary to obtain either Biophore [REDACTED] documents "on demand."

I. Legal Standard.

The Third Circuit defines "control" as the "legal right to obtain the documents required on demand." *Princeton Digital Image Corp. v. Konami Digital Entm't Inc.*, 316 F.R.D. 89, 90 (D. Del. 2016) (Burke, J.) (quoting *Inline Connection Corp. v. AOL Time Warner Inc.*, No. 02-272-MPT, 2006 WL 2864586, at *1 (D. Del. Oct. 5, 2006)); *see also Gerling Int'l Ins. Co. v. Comm'r of Internal Revenue*, 839 F.2d 131, 140 (3d Cir. 1988); *Power Integrations, Inc. v. Fairchild Semiconductor Int'l, Inc.*, 233 F.R.D. 143, 145 (D. Del. 2005). "In the absence of control by a litigating corporation over documents in the physical possession of another corporation, the litigating corporation has ***no duty to produce***."¹ *Gerling*, 839 F.2d at 140. In determining legal control over non-party documents, Third Circuit courts consider the corporate and contractual relationships between the party-litigant and non-party. *See, e.g., Princeton*, 316 F.R.D. at 93 (discussing and distinguishing cases finding control by a party-litigant over a non-party "wholly owned subsidiary" or "sister corporation"); *Gerling*, 839 F.2d at 140-41 (same); *Inline*, 2006 WL 2864586, at *3-4 (noting that "a contract provision which merely authorizes the party litigant's access to information that is in the possession of a non-party, without more, is insufficient to establish legal control in the Third Circuit"). "In the case of two *independent* corporate entities . . . production of documents would only occur when the respective business operations of each independent entity are 'so intertwined as to render meaningless' their distinct corporate identities." *Inline*, 2006 WL 2864586, at *3 (original emphasis) (quoting *Novartis Pharms. Corp. v. Eon Labs Mfg., Inc.*, 206 F.R.D. 392, 295 (D. Del. 2002)).

II. No Evidence of Control Under the Correct Legal Standard.

Plaintiffs attach twenty-one (21) exhibits to their opening letter brief, yet Plaintiffs fail to cite or quote a single statement providing Apotex a "legal right" to obtain documents from either Biophore [REDACTED] "on demand." *See Princeton*, 316 F.R.D. at 90; *Inline*, 2006 WL 2864586, at *1; *Gerling*, 839 F.2d at 140. Moreover, Plaintiffs cite no evidence that the business operations of Apotex, Biophore, [REDACTED] are "so intertwined as to render meaningless' their distinct corporate identities." *Inline*, 2006 WL 2864586, at *3. Thus, there is no genuine dispute that Apotex does not have the required "control" over either Biophore [REDACTED]

III. Plaintiffs' Arguments Do Not Establish Control.

A. Voluntary Production of Documents Does Not Establish Any Legal Right.

¹ Emphasis has been added unless otherwise noted.

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Plaintiffs state at least nine (9) times that Apotex produced Biophore documents. That is not true. To be clear, it was Biophore alone—not Apotex—that negotiated a stipulated agreement to produce documents in response to a subpoena to Biophore Pharma Inc. *See* D.I. 544; *Plaintiffs' Letter* at 1 (acknowledging Biophore voluntarily produced documents) (D.I. 750).² Moreover, even if Apotex had “selectively obtained” Biophore [REDACTED] documents (which Apotex did not),³ to the extent Plaintiffs imply that constitutes “control” over either third party, Plaintiffs cite no authority supporting their argument. At most, Plaintiffs cite to *Sanofi* (D.N.J. 2011) for their argument that Apotex somehow is using Biophore’s third party status as both “a sword and a shield.” But *Sanofi* is inapposite. In *Sanofi*, the dispute arose from Sandoz’s refusal to produce a 30(b)(6) witness to testify on activities performed by its “sister” company, Lek. *Sanofi-Aventis v. Sandoz, Inc.*, 272 F.R.D. 391, 392 (D.N.J. 2011). The *Sanofi* court considered evidence “of an even closer relationship between Sandoz and Lek . . . that goes beyond conventional business dealings,” including the fact that Lek projected itself to the public as a “Sandoz company.” *Id.* at 395. As a result, the *Sanofi* court held that “Sandoz cannot use its foreign affiliation with Lek as both a sword and a shield.” *Id.* at 396. Here, unlike *Sanofi*, there is no corporate familial relationship between Apotex and Biophore [REDACTED] or between [REDACTED] that could establish control, and Plaintiffs do not contend that any such relationships exist.

B. “Ability” to Obtain Documents Does Not Establish Any Legal Right.

Plaintiffs argue that Apotex must have the “ability” to “obtain[] and produce[] technical documents from Biophore,” because Biophore “freely provided XRPD documents to Apotex [REDACTED] in the ordinary course of business.” *Plaintiffs' Letter* at 2. However, under Third Circuit law, the mere fact that Apotex may obtain information from Biophore [REDACTED] if it had a business or other reason to do so is irrelevant to the issue of control” and certainly does not establish any legal right. *Inline*, 2006 WL 2864586, at *3. To the extent Plaintiffs are requesting that this Court adopt the Second Circuit’s “practical ability” standard, this Court has already rejected that approach. *See id.* at *2 (citing and quoting *Power*, 233 F.R.D. at 146 (“Cases in the Second Circuit go beyond defining ‘control’ as the *legal right* . . . and include an inquiry into the *practical ability* . . .” (original emphasis))).

Although Plaintiffs cite a number of cases to support their “ability” argument, Plaintiffs’ reliance on these cases is misplaced. For example, the *Princeton*, *Benicar*, and *Mushroom* cases all occurred in the context where a corporate familial relationship existed between the party-litigant and non-party entity. *See Princeton*, 316 F.R.D. at 90-91 (applying the Third Circuit’s two-pathway approach for finding control in “cases where a litigating company’s *sister corporation* possesses the desired documents,” and ultimately finding that the record presented did not establish

² Plaintiffs have never sought discovery of [REDACTED] by subpoena or through the Hague Convention.

³ Plaintiffs also seem to imply that Apotex had prior knowledge of and purposefully caused Biophore to delay production of the XRPD pattern for drug substance [REDACTED]. *See Plaintiffs' Letter* at 1; D.I. 750-5. Not true. Apotex was not aware [REDACTED] until after Apotex specifically asked Biophore in view of Plaintiffs’ opening expert reports. That Biophore produced the XRPD pattern in response to Apotex’s request does not create a legal right for Apotex to obtain hundreds or thousands of additional documents from Biophore on demand.

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control); *In re Benicar (Olmesartan) Prod. Liab. Litig.*, 2016 WL 5817262, at *3 (D.N.J. Oct. 4, 2016) (corporate affiliates); *In re Mushroom Direct Purchaser Antitrust Litig.*, 2012 WL 5199388, at *1 (E.D. Pa. Oct. 22, 2012) (corporate affiliates). As stated above, there is no corporate familial relationship between Apotex, Biophore, [REDACTED]. Moreover, the present matter is also clearly distinguishable from the *Moretti* case.⁴ In *Moretti v. Hertz Corp.*, the court found that “the relevant contractual provisions governing Defendants’ access to documents in the physical custody of their [non-party] Licensees do provide Defendants ‘the legal right or ability to obtain the documents . . . upon demand.’” 2018 WL 4693473, at *2 (D. Del. Sept. 30, 2018). Unlike in *Moretti*, there are no relevant contractual agreements between Apotex and Biophore [REDACTED] or between [REDACTED] Biophore, and certainly none that establish the required “legal right to obtain documents on demand.”

C. “Close Coordination” and “Free Flow of Information” Between Parties Do Not Establish Any Legal Right.

Plaintiffs argue that “close coordination” and “free flow of information” could “indicate[] control,” citing *Princeton, LG.Philips, Afros, and Mushroom. Plaintiffs’ Letter* at 2. However, none of those cases state that “close coordination” or “free flow of information” establishes a legal right to obtain documents on demand. In addition, the cases are clearly distinguishable from the present matter. Like *Princeton* and *Mushroom*, the *Afros* case occurred in the context where a corporate familial relationship existed between the party-litigant and non-party entity. *Afros S.P.A. v. Krauss-Maffei Corp.*, 113 F.R.D. 127, 129-30 (D. Del. 1986) (wholly owned subsidiary and parent). And, like the *Moretti* case, the *LG.Philips* case involved an agreement containing provisions that “confer[] . . . broad and unfettered contractual rights of access to information and documents” of the third parties. *LG.Philips LCD Co. v. Tatung Co.*, 2007 WL 9771322, at *5-6 (D. Del. Feb. 14, 2007). As explained above, there are no such corporate familial or contractual relationships in the present case that establish a legal right for Apotex to obtain documents from Biophore [REDACTED].

D. Disclosure of Individuals with Potential Knowledge Does Not Establish Any Legal Right.

Plaintiffs argue that Apotex should produce Biophore [REDACTED] documents because they are identified in Apotex’s rebuttal witness disclosures. Yet, again, Plaintiffs cite no authority for their novel argument. And, again, there is no evidence of the “control” necessary for Apotex to obtain hundreds or thousands of Biophore [REDACTED] documents on demand.

* * *

Apotex respectfully requests that the Court deny Plaintiffs’ motion to compel.

⁴ Plaintiffs also cite to *Love v. Dep’t of Corrections*, which is even less relevant than Plaintiffs’ other cited cases. The parties in *Love* were not corporations, but rather an inmate who moved to compel prison officers to produce documents in the possession of the non-party State, where the court found that the State’s obligation to indemnify its employees established the requisite legal control. 2017 WL 3477864, at *4-6 (D.N.J. Oct. 4, 2016).

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Respectfully submitted,

/s/ John C. Phillips, Jr.

John C. Phillips, Jr. (No. 110)

cc: Plaintiffs' Counsel of Record (via CM/ECF & Email)